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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/484,577	01/18/2000	Lynn K. Gordon	07419-029001	9856

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EXAMINER
ROARK, JESSICA H

ART UNIT	PAPER NUMBER
1644	21

DATE MAILED: 05/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/484,577	GORDON ET AL.	
	Examiner	Art Unit	
	Jessica H. Roark	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 February 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,9,10,14,28,29,43,45,46 and 50-62* is/are pending in the application.

4a) Of the above claim(s) *46,50,61 and 62* is/are withdrawn from consideration.

5)☒ Claim(s) *4* is/are allowed.

6)☒ Claim(s) *1-3,9,10,14,28,29,43,45 and 51-60* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *18 January 2000* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

RESPONSE TO APPLICANT'S AMENDMENT

1. Applicant's amendments, filed 2/11/03 (Paper No. 20), is acknowledged.
Claims 11-13, 16 and 47-49 have been cancelled.
Claims 5-8, 15, 17-27, 30-42 and 44 have been cancelled previously.
Claims 1-4, 9-10, 14, 28-29, 46 and 50 have been amended.
Claims 51-62 have been added.

Claims 1-4, 9-10, 14, 28-29, 43, 45-46 and 50-62 *are pending.*

2. Newly submitted claims 61 and 62 are directed to an invention that is independent or distinct from the invention originally claimed because:

Claim 61 is drawn to an array of nucleic acids, classified in Class 435, subclass 970.

Claim 62 is drawn to a method of detecting the presence of SEQ ID NO:3 by primer amplification, classified in Class 435, subclass 6.

The inventions are distinct, each from the other because: The elected Invention of the nucleic acid of SEQ ID NO:3 (Group II). The array of claim 61 is a distinct product comprising nucleic acids on a test strip. The Invention of Group II and the method of claim 62 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acid can be used to express the protein, in addition to the detection method recited.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 61-62 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 46 and 50 have been previously withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03 (Paper No. 18).

Claims 1-4, 9-10, 14, 28-29, 43, 45 and 51-60 *are under consideration in the instant application.*

3. It is noted that method claims *commensurate in scope* with an allowable product claim would be eligible for rejoinder practice.

4. This Office Action will be in response to applicant's arguments, filed 2/11/03 (Paper No. 20). The rejections of record can be found in the previous Office Actions (Paper Nos. 14 and 18).

It is noted that New Grounds of Rejection are set forth herein.

Specification

5. The disclosure stands objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

A hyperlink was found at least on page 22 at line 26. Applicant is requested to carefully review the specification for additional hyperlinks.

Claim Objections

6. Claim 9 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim, or amend the claim to place the claim in proper dependent form, or rewrite the claim in independent form.

The definition of a "nucleic acid" provided on page 11 of the specification does not appear to encompass labeled nucleic acids. Thus a nucleic acid that is labeled is broader in scope than the nucleic acid in claims 1, 4 or 45.

7. Claim 9 is objected to for the following informality: the claim recites "that selective hybridize" when it appears -- that selectively hybridize -- was intended. Appropriate correction is required.

Claim Rejections - 35 USC § 112 second paragraph

8. The following is a quotation of the second paragraph of 35 U.S.C. 112.

> *The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.*

9. Claims 1-3, 9-10, 14, 28-29 and 51-60 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims as amended now recite nucleic acids that "selectively hybridize". This phrase is ambiguous because in order for the metes and bounds of the claimed to be established, the conditions under which the nucleic acid is hybridized must be clearly defined (10 times background under what conditions?). Although general conditions of hybridization are disclosed in the specification (e.g., original claim 9, pages 15-16 and 20-21), these conditions are not clearly limited.

It is suggested that Applicant amend the claims to recite a particular set of hybridization and wash conditions, such as those exemplified on pages 20-21of the specification, to overcome this rejection.

Applicant is reminded that the amendment must point to a basis in the specification so as not to add any new matter. See MPEP 714.02 and 2163.06

Claim Rejections - 35 USC § 112 first paragraph

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 1-3, 9-10, 14, 28-29, 43, 45 and 51-60 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The following *written description* rejection is set forth herein.

Applicant's arguments, filed 2/11/03, have been fully considered, but have not been found convincing. Applicant's arguments are addressed below in the context of a reiteration of the rejection of record, as applied to the amended and newly added claims. The rejection of record may be found in Paper No. 18.

The nucleic acid of SEQ ID NO:3 was identified using a differential screen of genomic DNA for sequences associated with Giant Cell Arteritis (GCA) (e.g., specification pages 29, 78-80). When the nucleic acid of SEQ ID NO:3 was expressed as a fusion protein consisting of SEQ ID NO:4 and GST, the fusion protein was differentially bound by sera from GCA patients (e.g., pages 80-84 and Figure 3).

Applicant has also previously provided on 3/20/02 a Declaration under 37 CFR 1.132 by Dr. Gordon stating that a pair of primers using sequence from within SEQ ID NO:3 amplified DNA from GCA+ arterial samples, but did not amplify GCA negative samples.

The instant claims are drawn to nucleic acids sharing various percent sequence identities to a nucleic acid consisting of SEQ ID NO:3 and selectively hybridizing to SEQ ID NO:3 or its complement under some undefined hybridization conditions (e.g., independent claim 1); as well as to fragments thereof (e.g., claims 2-3, 9-10) and vectors and host cells comprising (e.g., claims 14 and 58). Claim 45 is drawn to a nucleic acid encoding a polypeptide as set forth in SEQ ID NO:4 and consisting essentially of SEQ ID NO:3. Kits comprising these nucleic acids are also claimed (e.g., claims 28-29, 59-60).

The Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement make clear that the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the genus (Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001, see especially page 1106 3rd column).

The specification does not disclose what gene SEQ ID NO:3 is from. Further, the specification does not disclose that SEQ ID NO:3 is drawn to a full length open reading frame. Claim 45 reciting the "consisting essentially of" and "encoding" (i.e., "open") language reads upon complete gene sequences having in common a nucleotide sequence of SEQ ID NO:3 from any source. With the exception of SEQ ID NO:3, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides, regardless of the simplicity of the method of isolation, absent further guidance. Since the claimed genus encompasses undisclosed genes, partial genomic sequences, and genes yet to discovered, the disclosed structural feature (i.e., the nucleic acid consisting of SEQ ID NO:3 encoding the polypeptide consisting of SEQ ID NO:4) does not constitute a substantial portion of the claimed genus.

In addition, the claims now recite a nucleic acid having 75% (or 80, 85, 90, 95 or 98%) sequence identity over some undefined length of SEQ ID NO:3 and hybridizing to SEQ ID NO:3 or its complement as part of the invention. However, there does not appear to be an adequate written description in the specification as-filed of the essential structural feature of the instantly recited nucleic acids, nor a correlation between a particular structure and function. The genus of nucleic acids which would hybridize to SEQ ID NO:3 or its complement is very large, encompassing not only sequences with polymorphisms and mutations compared to SEQ ID NO:3, but also sequences having minimal shared sequence identity to SEQ ID NO:3.

The amendment of the claims to recite that the nucleic acid also has some percent identity shared with SEQ ID NO:3 limits the genus very little since it is not necessary for the percent identity to be over the full length of the nucleic acid. In addition, as discussed below in response to Applicant's arguments, the amendment of the claims to recite that the nucleic acid selectively hybridizes to SEQ ID NO:3 does not impart a functional requirement to the variant nucleic acid sequences. Consequently, SEQ ID NO:3 and its complement again does not appear to constitute a representative portion of the claimed genus.

Since these various nucleic acids are not adequately described for the reasons set forth supra and of record, the Examiner again notes that fragments of these nucleic acids also lack adequate written description, as do host cells and kits comprising.

Applicant comments that although SEQ ID NO:3 was isolated from a genomic DNA library, it is not clear that it is a genomic DNA, arguing that the DNA sequence may also be an exogenous nucleic acid from an invading bacterial or viral agent.

The Examiner acknowledges that SEQ ID NO:3 may not be mammalian DNA. However, this observation by Applicant does not alter the fact that claim language which fails to limit the DNA to exclude naturally occurring flanking sequences read on undisclosed genes, and that the instant sequence fails to set forth an open reading frame.

Applicant also reviews Example 14 of the Patent Office's Revised Written Description Guidelines and the Trilateral Project regarding DNA claim language. Applicant summarizes that each of these guidelines indicates that a species can support a claim to a genus of variant sequences when structure and function are provided in the claim. Applicant asserts that the instant claims meet this requirement because the claims recite a specific structure (a nucleic acid having at least 75% sequence identity to SEQ ID NO:3) and function (selective hybridization to SEQ ID NO:3 or its complement).

Function requires some activity essential to the operation of the claimed invention. In the instant case, Applicant's invention is that a protein expressed using the full length sequence set forth in SEQ ID NO:3 can be used to detect antibodies diagnostic of GCA; that amplification of SEQ ID NO:3 using probes that are internal fragments of SEQ ID NO:3 can be used to diagnose GCA; and that SEQ ID NO:3 can be used to detect the presence of nucleic acid sequences associated with GCA by hybridization to the GCA-associated nucleic acids in a sample (e.g., specification pages 4-5).

However, the asserted "function" of selectively hybridizing to SEQ ID NO:3 or its complement is not a function as set forth in the Guidelines because hybridization without some requirement that an end result is obtained is simply an indication of the structure of the nucleic acid. Thus the instant claims simply define the structure of the claimed nucleic acids in terms of not only percent identity, but also sequence compatible with hybridizing to SEQ ID NO:3.

Applicant further comments that the utility of selective hybridization to SEQ ID NO:3 has been previously acknowledged by the Office. However, Applicant's attention is called to Paper No. 18 at paragraph #4. The utility acknowledged by the Examiner was not hybridization to SEQ ID NO:3, but rather that the nucleic acids could be used to diagnose GCA.

Applicant's assertion that the instant claims have been limited to provide a defined structure, as suggested by the Examiner in Paper No. 18, page 5 at lines 27-28 is also noted. However, other than claim 4, the instant claims still encompass sequence variants and therefore lack a defined structure.

Thus for the reasons set forth previously in Paper No. 18 and elaborated upon supra with respect to the amended and newly added claims, the instant claims do not appear to meet the Written Description requirement.

Conclusion

12. Claim 4 appears to be allowable.

13. It is again noted that claims limited to *internal* fragments of SEQ ID NO:3 would appear to have adequate written description in the specification as filed and be enabled for a use that was detecting GCA-associated nucleic acids.

As also acknowledged previously, method claims which are commensurate in scope with an allowable product claim would be eligible for rejoinder practice.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica H. Roark, whose telephone number is (703) 605-1209. The examiner can normally be reached Monday to Friday, 8:00 to 4:30. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached at (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

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May 6, 2003

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